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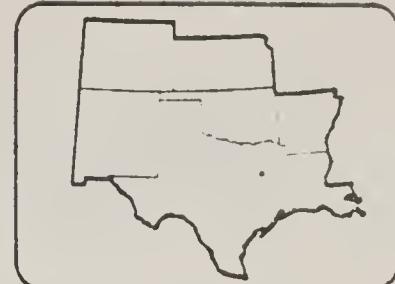
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UNITED STATES DEPARTMENT OF AGRICULTURE
1100 Commerce Street • Room 5-C-40 • Dallas, Texas 75242
Telephone (214) 767-0094 Bryson



August 20, 1980

USDA and FDA Issue Joint Statement on Nitrite Study

Commissioner of the Food and Drug Administration Jere E. Goyan and Assistant Secretary of Agriculture Carol Tucker Foreman issue the following statement:

"A group of independent pathologists has completed an extensive review of the study conducted at Massachusetts Institute of Technology that led us in 1978 to consider the need to phase out nitrite as a preservative in cured meats and poultry.

"The pathologists evaluated 50,000 tissue slides from the 2,000 rats in the study and found a 'much lower incidence of lymphoma'--cancers of the lymph system--than was originally reported.

"A committee of scientists from several government agencies has evaluated the pathologists' review and has concluded that insufficient evidence exists to support a conclusion that nitrite induced cancer in the rats, based on the MIT study.

"As a result of the review and evaluation, we have concluded there is no basis for FDA or USDA to initiate any action to remove nitrite from foods at this time.

"At the same time, we will continue to pursue our efforts to eliminate preformed nitrosamines from foods. Nitrosamines are chemicals formed when nitrite combines with naturally-occurring substances known as amines.

"Nitrosamines are known carcinogens. Efforts to eliminate or reduce nitrosamines from such disparate products as bacon and beer have been highly successful.

"The Massachusetts Institute of Technology study reported in 1978 was undertaken after an earlier study suggested that nitrite itself might be carcinogenic. FDA contracted with Paul Newberne of MIT, a leading expert in the study of nutrition-induced disease, to explore the possibility in a large and thorough study.

"The MIT research was quite extensive. It involved 1,381 rats that were fed nitrite, plus 573 controls."

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"That study was made public by FDA and USDA in August, 1978. In it, Newberne reported that the nitrite-fed rats had an increased rate of cancer of the lymph system. Among the rats fed nitrite, 12.5 percent were reported to have been found with lymphomas, compared to 7.9 percent of the control rats. (Dr. Newberne later revised these figures to 10.5 and 5.75 percent respectively.)

"The study had many possible ramifications. Nitrite is the preservative and color fixative used in bacon and all other cured meats such as hot dogs, bologna, corned beef and ham.

"Nitrite serves a health purpose in that it inhibits the growth of bacteria, thereby preventing the formation in meat of a toxin that can cause botulism, a deadly form of food poisoning. An estimated \$12.5 billion worth of food--seven percent of our food supply--has nitrite added to it. In many respects, the nationwide production and distribution system for processed meats, poultry, fish and other products depends on the use of nitrite. Consumers, too, are accustomed to the margin of safety that nitrite provides in such products as hot dogs and lunch meats which are eaten cold or only after slight heating.

"When the MIT study was concluded in 1978, FDA and USDA reached the tentative conclusion that nitrite might cause cancer. They therefore initiated two courses of action:

--first, they tentatively decided that, if nitrite were shown to cause cancer, it could not be abruptly eliminated from food processing, unless an alternative preservation method was available to protect against botulism. Therefore, the agencies began developing a proposed series of steps that might be taken to reduce and ultimately eliminate nitrite, as the research might justify. The agencies asked the Department of Justice whether the proposed plan was possible under current law. The Department of Justice said the proposed phaseout plan would not be possible under current law, and that if nitrite were found to be carcinogenic, an immediate prohibition of its use as a food additive would have to be proposed to the agencies. The agencies subsequently developed legislation that would have tied a phaseout of nitrite, if justified by the research, to development of an alternative preservation method. We see no need at the present time for Congressional action, but we will keep the appropriate Congressional committee informed as new data become available.

--second, after questions were raised first by government and subsequently by non-government scientists about the validity of the MIT study, the agencies concluded there was need for a thorough outside review of it. FDA therefore formed the Interagency Working Group on Nitrite Research, with scientists from FDA, USDA, the National Cancer Institute and the National Institute of Environmental Health Sciences.

"FDA then contracted with a consortium of medical school-based pathologists known as Universities Associated for Research and Education Pathology (UARED) for a slide-by-slide review of the tissues diagnosed in the MIT study as malignant and those diagnosed as normal.

"A preliminary evaluation by the pathologists in the Working Group of a random sample of tissue slides revealed significant differences of opinion as to diagnoses. Therefore, the group recommended a full-scale pathology review of the MIT study.

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"Each of the 50,000 slides was reviewed by one or more pathologists who did not know the original diagnosis. Where the new diagnosis differed from Newberne's, a panel of three or more pathologists reviewed the disputed slide independently and then tried to reach agreement. If they could not reach unanimous agreement, the case was referred to a seven-person Joint Committee of Experts.

"This committee performed other functions as well, such as maintaining quality control by checking other selected slides, by looking at all unusual cases and by assuring that the pathologists, though in different locations, were using the same standards and were operating without knowledge of the original diagnoses.

"UAREP and its joint committee found a 'much lower' number of lymphomas than had been diagnosed by Newberne. Some of the tissue slides diagnosed by Newberne as lymphomas were interpreted by the reviewing pathologists as being noncancerous lesions; other slides were interpreted to be histiocytic sarcomas--a type of cancer that has appeared randomly in other strains of rats, is of unknown cause, and has no counterpart in humans.

"UAREP's review was statistically analyzed by FDA and evaluated by the Interagency Working Group on Nitrite Research, which is chaired by Albert Kolbye, Jr., associate director for toxicology of FDA's Bureau of Foods, and Gary Flamm, FDA's acting deputy associate commissioner for Health Affairs (Science).

"The Interagency Working Group reported to us that 'insufficient evidence exists to support the conclusion that sodium nitrite per se fed to rats causes cancer, based on the MIT study'.

"The working group concluded that the incidence of lymphomas observed by the UAREP pathologists is similar to those usually seen in this strain of rat. There was no statistical significance in the incidence of lymphomas in the rats fed nitrite when compared to those which were not.

"The group said it could not find sufficient evidence to show a causal relationship between the appearance of histiocytic sarcomas in the experimental rats and nitrite. Histiocytic sarcomas were found scattered in both rats that were fed nitrite and those that were not.

"The group said it would not recommend that a similar feeding study be initiated at this time, but rather that all relevant data on nitrite be reviewed before additional studies are considered.

"Accordingly, we have decided to contract with the National Academy of Sciences to assist in such a review, and to also evaluate any plans for studies that the agencies may decide are needed in the future. Initially, NAS will conduct an independent assessment of all available scientific information about nitrite and will analyze scientific data and develop a research agenda on potential alternatives to nitrite as a preservative in meats and poultry."

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